

UNITED STATES OF AMERICA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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GMP MODERNIZATION PUBLIC MEETING

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WEDNESDAY

JULY 21, 2004

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CHICAGO, ILLINOIS

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The GMP Modernization Public Meeting met
at The Chicago Marriott Hotel, 540 North Michigan Avenue,
at 2:00 p.m., Dr. Donald Zink, facilitator.

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PRESENT:

Dr. Donald Zink, FDA

Dr. Richard Williams, FDA

Bruce Tompkin, ConAgra Refrigerated Prepared Foods

Terence Furlong, Food Allergy & Anaphylaxis Network

Marlena Bordson, Illinois Department of Public Health

Brian Hendrickson, FDA

Marie Falcone, FDA Central Region, Small Business

Representative

Dr. Clark Nardinelli, FDA, Team Leader for Economics,

CFSAN

Dr. Crawford, Acting Commissioner of Food and Drugs

Audience:

Nega Beru, AFDO

Hari Soni

Betsy Blair

Dr. John E. Rushing, Professor of Food Service

Joseph Corby, Director, Division of Food Safety &

Inspection Services

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P R O C E E D I N G S

(2:00 P.M.)

MR. ZINK: I am Don Zink and I am with the FDA Center for Food Safety and Applied Nutrition. I'm involved in the agency's internal working group on food good manufacturing practices modernization, and I would like to welcome everybody to our second of three public meetings on good manufacturing modernization.

This is a very important initiative within the agency. Dr. Lester Crawford, our acting Commissioner, began an across-the-board review of good manufacturing practices regulations in each of the FDA centers, and I guess the first really to start this was SETA, our center for drugs, and they are certainly well ahead of CFSAN, but it was expected that each of these centers would take several years, internally examining good manufacturing practices, and in fact, we began this internally almost two years ago, looking at the regulations and the effectiveness of them, and research gaps and needs, and doing some research, and we're going to tell you a bit about that today.

First, I'd like to give you some housekeeping information. There are restrooms located close by, in the far left corner, men's restroom, far right corner, women's

1 restrooms, in the foyer outside the meeting room. When it
2 comes time to ask questions, if you would, come to the
3 microphone, clearly state your name and your affiliation.
4 The proceedings of today's meeting will be transcribed.
5 Everything that we get electronically or in print will go
6 to our Docket managements group and be entered into the
7 public record, and will be available for anyone to see. A
8 transcript of today's meeting will be available
9 approximately oh, fifteen days after today. We will put
10 everything we can on our internet site, and generally try
11 to make this as absolutely transparent as we possibly can.

12 I would like to, again, emphasize the
13 importance we attach to this. We think good manufacturing
14 practices are a foundation of all other food safety
15 programs. We have a lot of people here today from the
16 agency here in Chicago. We have our Moffet Center research
17 group, at the National Center for Food Safety and
18 Technology. We have a number of our staff from there
19 today. We have a number from Washington, the CFSAN office.

20 And I'd also like to recognize Joann Givens, a district
21 director from Detroit, is here with us today, and we have
22 representatives of the Chicago District as well, so this is
23 something that we really want all of our stakeholders,
24 internally and externally, to be involved in.

1 I want to say, before we begin, I want to
2 clarify what we mean by good manufacturing practices. When
3 you hear the term "current good manufacturing practices,"
4 you think of 21CFR, Part 110, and certainly that is the
5 current good manufacturing practices and FDA regulations,
6 but a word you'll hear or a phrase you'll hear used around
7 the center these days is universal preventive controls.
8 What good manufacturing practices really are is they are
9 those controlled procedures and practices that you would do
10 to preserve the wholesomeness and safety of food products
11 manufactured under the agency's purview. And, we want you
12 to think when you're thinking about good manufacturing
13 practices and an GMP regulation for the future, we want you
14 to think in the broadest possible sense.

15 What we want to hear about and understand are
16 current state-of-the-art practices in industry for good
17 manufacturing practices. What is it that's necessary to do
18 universally in the food industry to ensure the
19 wholesomeness and safety of food products. By preventive
20 control, emphasis is on the word preventive. We continue
21 to see, and you'll hear more about this, numerous Class I
22 and Class II recalls, a great many of which aren't failures
23 of a particular Hassip plan, for example, they're the sorts
24 of mistakes that are made when there is not an operating

1 procedure or management oversight or control in place.

2 What I would call GMP-types of failures, and this is what
3 we want you to think about, how we can prevent these.

4 What sorts of things could we, by regulation,
5 put in place that would give greater visibility, greater
6 importance, and hopefully spur compliance with having these
7 kinds of preventive controls in place. And finally, I want
8 to say we're not coming in here with a draft regulation in
9 our back pocket or a preconceived idea of what we want to
10 do. Obviously we've discussed this.

11 We've been working on this for several years
12 inside the agency, so we have some ideas. But we genuinely
13 wanted to encourage some meaningful input and some fresh
14 ideas. Now is the time to share your thoughts with us. We
15 have a public comment period that's open. You can send in
16 written comments to Dockets. That's open until September
17 the 10th. And as soon as the Public Comment period closes,
18 we're going to get right to work on a modernization of the
19 GMPs.

20 We'll begin the rule making process formally at
21 that time.

22 What I'd like to do is dive right into our
23 agenda. I mentioned that this is very important to the FDA
24 and that Dr. Crawford had initiated this. Dr. Crawford

1 opened our first public meeting in Washington on Monday.
2 He's not able to be here for this meeting, but we have his
3 video presence, and so, with your indulgence, and if I get
4 the technology to work right, we'll have the, we'll give
5 the floor to Dr. Crawford.

6 DR. CRAWFORD: It's called the current good
7 manufacturing practices in manufacturing, packing or
8 holding human food. These rules, which are entitled 21,
9 Part 110 of the code of Federal Regulations no longer serve
10 that purpose as well as they should. They've been there
11 and have not been revised for 20 years, and during that
12 time as we all know, much has changed in the food industry
13 as well as in the eating habits of consumers.

14 Since the GMPs were last updated, food
15 producers have developed a seemingly endless and constantly
16 changing variety of processed, packaged and refrigerated
17 products, and Americans have made them a big part of their
18 diet. Portable soup, drinkable yogurt, squeezable peanut
19 butter and bagged lettuce salads did not exist 20 years
20 ago. Neither did low carb foods, Tex Mex foods or vanilla
21 sodas, all of which are today bestsellers. Another
22 significant addition to our menu is fresh produce imported
23 in and out of season from around the globe. And although
24 our food supply is as safe as any in the world, over the

1 past 20 years we've seen an emergence of new food
2 pathogens.

3 In addition, we have to contend with the fact
4 that our consumers have become far more conscious of the
5 hazards of food allergens than was the case two decades
6 ago. All of this makes the need a demand for protection
7 against food associated risk greater than ever. As an
8 agency whose per view includes 80 percent of this nation's
9 food supply, we therefore recently took a close look at how
10 well the food GMPs still ensure the safety and
11 wholesomeness of what we eat.

12 We conducted three studies focused on the types
13 of hazards associated with the current manufacturing and
14 processing practices and on the available controls to
15 prevent these risks. One of these studies reviewed the
16 extensive scientific and technical literature on this
17 issue.

18 A second paper summarized views with solicited
19 from experts an extensive knowledge and experience in this
20 area. And the third survey examined the food product
21 recalls in the United States from 1999 to 2002. I'll take
22 just a minute to give you the highlights of this survey
23 which included 842 recalls, 51 percent of which were Class
24 I hazards that can cause death or serious injury, and the

1 rest were Class II, whose health consequences are
2 reversible or temporary. The most striking finding of this
3 inquiry was that 715 of the recalls, 85 percent of the
4 total probably occurred due to GMP-related shortcomings.
5 That included improper or inadequate labeling which
6 accounted for about a half of the recalls, and microbial
7 contamination, which was the reason for about one-quarter
8 of the total.

9 Among the most frequent process at level
10 problems were ineffective employee training and inadequate
11 standard operating procedures. These results and the
12 information gathered in the two other surveys made clear
13 that the food GMPs need updating. One obvious possibility
14 is adoption of modern sanitation measures in the production
15 of prepared foods, which are usually consumed weeks after
16 they leave the production facility. Employee training and
17 education is another area that may need improvement. But
18 what changes the GMPs may or may not require is not a
19 decision we want to make without consulting with you, our
20 stakeholders.

21 Stakeholder input is a firmly imbedded
22 principle in FDA's traditional decision-making process that
23 we follow rigorously. We, therefore, scheduled three
24 public meetings to discuss this issue. One in College

1 Park, Maryland on July 19. One in Chicago on July 21, and
2 the final one is in San Jose, California on August 5. What
3 do we want to accomplish at these meetings? We have two
4 overriding goals. One, we want to explore the best,
5 potentially most effective science-based measures that
6 approaches that would help manufacturers reduce the
7 likelihood of producing foods that can be injurious to
8 consumers.

9 Without ignoring the problems involving
10 labeling, we want to primarily address the most serious
11 risk of contamination with chemical, microbiological or
12 physical impurities. In dealing with these issues, we will
13 be careful to distinguish between practices that may
14 directly impair food safety and those whose effects are
15 likely to be marginal. Our guiding principle will be
16 reliance on science-based systems that are guided by
17 evidence, both regarding problems and their effective
18 solutions.

19 The outcome we seek is a set of targeted
20 requirements that will enable manufacturers to focus their
21 resources on strengthening the safety of their products. A
22 corollary goal, and I want to emphasize this, is to elicit
23 your ideas on just what should be changed in the GMPs and
24 how. Of course, we'll be drawing on appropriate literature

1 and on the experience of food technologists,
2 microbiologists and industry professionals of all kinds.
3 But extensive thoughtful input from all of our stakeholders
4 is critical. We need your full support for this initiative
5 and your help.

6 As a general background, I should add that
7 updating the food GMPs is only one facet of a broad
8 modernization process we've recently initiated with a
9 similar reform of the pharmaceutical GMPs. Eventually we
10 intend to modernize the GMPs of all industries whose
11 products are regulated by FDA.

12 Yet another innovation we've recently launched
13 is the development of standards and methods that would
14 enable drug sponsors to better estimate whether their
15 medications will qualify for marketing. This is an
16 enormously important issue in drug manufacture, where only
17 eight percent of new compounds eventually achieve FDA
18 approval and reach patients.

19 We're also considering a similar initiative to
20 reduce the technical, regulatory and marketing
21 uncertainties faced by food producers who contemplate the
22 development of new products. A common denominator and
23 overarching aim of these and many other FDA initiatives is
24 to reduce and manage the risk effecting the health of our

1 public, and thereby advance the vitality of our nation.
2 Your participation in today's meeting and discussions is a
3 meaningful contribution to this effort. I very much
4 appreciate that.

5 Thank you for coming and I am looking forward
6 to your information and views.

7 DR. ZINK: I would like to introduce our first
8 speaker, Dr. Richard Williams. Richard is a scientist in
9 the Center for Food Safety and Applied Nutrition. He
10 joined FDA in 1980 after receiving his Ph.D. in Economics
11 from Virginia Tech, and he's currently the Director of the
12 Division of Market Studies in CFSAN. This is a division
13 that includes a variety of scientists, statisticians,
14 epidemiologists, physicians, sociologists.

15 This is that division of the Center that
16 conducts much of our outward reaching research, the
17 economic analysis of cost benefit of rules, et cetera.
18 They do very diverse research, even things related to first
19 amendment issues, labeling, biosecurity, gathering and
20 analyzing epidemiological data, and Richard has been
21 responsible for the analysis of the impacts of regulations,
22 or things like nutrition labeling and education act. He's
23 an expert in various regulatory matters pertaining to the
24 U.S./Canada Free Trade Act. He helped negotiate that, and

1 he's responsible for developing a series of courses in risk
2 analysis and food risk management as a part of our
3 relationship with the University of Maryland, a center we
4 call GIFSAN, and our staff college. He's an expert in risk
5 analysis and risk management and he's published numerous
6 papers on risks and trade-offs, and is an expert on
7 regulatory flexibility for small businesses. Richard?

8 DR. WILLIAMS: Good Afternoon. Thank you, Don.

9 As Don says, my portion of this will be to talk about the
10 research that we've been doing that is ongoing right now
11 into preventive controls. And this research is just one of
12 the many inputs that will go into the final decision on how
13 we reform the good manufacturing practices. As Dr.
14 Crawford said, we hope that any reform we do will be
15 science-based and it will be based on evidence of things
16 that work, and I think that's a recurring theme that you
17 will hear.

18 Okay, so how do we start? We always start by
19 saying what is the question that we're being asked to
20 answer in terms of research, and the question that we think
21 we're being asked to answer is what significant hazards are
22 associated with FDA regulated food that can be addressed by
23 preventive controls, and then what are the most effective
24 preventive controls for those hazards? And as always, we

1 do consider sort of the big three grouping microbial
2 hazards such as pathogens, chemical hazards such as
3 allergens, and physical hazards such as glass or metal.

4 So that's the question that we were asked to
5 answer and as Dr. Crawford said, we have done three
6 studies, and I'll go over those a little bit more in
7 detail.

8 This next slide really talks about sort of how
9 we think about the evidence that we need to go after good
10 manufacturing practices and there are sort of two big
11 sources of evidence that we went after. The first is what
12 are the current problems right now in food processing that
13 are related to good manufacturing practices? In other
14 words, what things are happening right now? There are
15 outbreaks of illness and they could either be because,
16 simply parts of the food industry are not following the
17 good manufacturing practices, or maybe it's things that
18 should be in the good manufacturing practices but that
19 aren't there now.

20 So that's one type of evidence that we want.
21 What hazards are out there now that are related to
22 preventive controls more broadly? The other thing is we
23 want to make sure that when we go to rewrite the good
24 manufacturing practices, that we don't lose anything that's

1 effective now. In other words, there may be practices that
2 manufacturers are using now that are either in the GMPs
3 again or not in the GMPs. They are actually solving
4 problems and we want to make sure that we capture those as
5 well to make sure that we get a complete set of good
6 manufacturing practices that are effective and that will
7 address the problems.

8 Okay, so let me go through the first one now,
9 the current problems. As Dr. Crawford said, we are in the
10 process of conducting these three studies: a literature
11 search, an expert elicitation and a recall study, and we
12 regard stakeholder input as just another source of data
13 because we will be getting that also. These studies will
14 be completed around the end of September. However, we will
15 have a summary of the overall findings, and these findings
16 will not change, up on our website within about a week or
17 two, and we would very much like for you to read them and
18 comment on them and tell us what you think.

19 In addition, as I said, we're going to look at,
20 you know, what potential problems are there that are being
21 solved right now that we ought to capture in the good
22 manufacturing practices. We intend to survey the food
23 industry starting sometime either, I think, this fall or
24 winter, as to what all the existing practices are that

1 people are doing, and that's going to be focused not just
2 on good manufacturing practices, but again, more broadly on
3 preventive controls. And again, stakeholder input we hope
4 will play a big role in what's working now, what
5 manufacturers are doing.

6 Okay, let me go through the individual studies.

7 The literature survey, interestingly about three-quarters
8 of the literature that was related to preventive controls
9 addressed microbial hazards, about a quarter addressed
10 chemical hazards and virtually nothing on physical hazards.

11 Two of the big repeated themes that we found in
12 the literature, one was poor worker hygiene was a leading
13 problem in food manufacturing plants. The other one that
14 was at least somewhat of a surprise to me was that training
15 was mentioned over and over and over again. The absence of
16 effective training, and they mentioned various reasons why
17 the training might not be effective.

18 Language barriers, for example. I know in my
19 county, in Fairfax, Virginia, in the retail food industry
20 they speak a 120 different languages. I'm sure food
21 manufacturers have problems with this as well. A lot of
22 discussion about whether or not generic training is needed,
23 or more specific training that's plant related, and even
24 getting very specific on what training is needed in

1 hygiene, cleaning, pest control and preventive maintenance.

2 More findings, contamination of raw ingredients
3 in the literature was seen to be a big problem, whether it
4 was incoming raw materials or actual in-plant
5 contamination. And then, a lot of literature has emerged
6 recently on allergens, allergen contamination by raw
7 materials. Residue problems where the residues aren't
8 removed, and label review policies, another thing that very
9 easily could be in the good manufacturing practice rule.
10 It was found that not a lot of plants had good label review
11 policies in some of the literature. And finally, design.
12 Either plant design where you had zoned areas that led to
13 cross-contamination. They were improperly zoned. And
14 equipment designs. Some literature on that where you have
15 niches and equipment is just simply difficult to find.

16 Okay, the next study we did was an expert
17 elicitation. This was a method for eliciting data from
18 experts. It was actually developed in World War II and
19 it's been adapted in the risk analysis field and we made
20 use of it. It's just simply a method for getting
21 information from experts and getting them to agree on
22 things. We are in the process now of just finishing up
23 four rounds of interviews.

24 We had seventeen experts, national experts that

1 are from around the country, experts in microbiology,
2 experts in food processing and so forth. And what we asked
3 them to do was tell us what the most important risks are
4 and then what are the most important and effective controls
5 for the food industry. We asked them to do it both
6 generally and by sector. And let me give you just a little
7 bit of an overview as to what they found. Again, the theme
8 of training came up.

9 Training, training, training, and in this case,
10 the experts felt that everybody needed to be trained. That
11 employees needed to be trained, managers needed to be
12 trained and suppliers needed to be trained. Again, this
13 finding of training went all through the three studies.
14 The experts felt that record keeping for standard operating
15 procedures was necessary. Another interesting finding that
16 cleaning needed validation, as to whether or not your
17 cleaning SOPs were working. Periodic audits of facilities
18 and raw materials. Sanitation SOPs and environmental
19 sampling.

20 Preventive maintenance programs. Again, labor
21 review and verification, again related to allergens. And
22 finally, one really interesting thing is they thought that
23 firms needed incentives from FDA to comply. Don't know how
24 we'll handle that one. Okay. And then last was the recall

1 study. Now the previous two studies were done for us by a
2 contractor and are being finished. The recall study was
3 one we did in-house by our epidemiology team, and as Dr.
4 Crawford mentioned, we have done Class I and Class II
5 records. You'll see more recalls than he mentioned there
6 because he taped his remarks earlier and we've been working
7 away. We actually have done 1,055 recalls and as he said,
8 about 85 percent of the recalls were due to GMP violations
9 or labeling. And a big percentage was incorrect packaging
10 or labeling.

11 Again, you see that theme, ineffective employee
12 training, 33 percent, standard operating procedures for
13 processes failed and so on. Contamination of raw
14 materials, mistaken or excess addition of chemicals, and
15 ineffective use of sanitation principles. The way we did
16 this study is with Don Zink here and others, we actually
17 went through the recalls and they went to look for these
18 root causes of what actually caused the problem in the
19 plant. So that's been taking them quite some time. Again,
20 we will have that, we will have the results of all three of
21 these up I hope in a week or two. You can look on our
22 website for it, and the final studies will not be done
23 until the end of September.

24 That's not all we're doing to do. As Don

1 mentioned, we have a staff of economists who will be
2 looking at the costs and benefits of all of the different
3 regulatory options for preventive controls. We're also
4 going to need, and you're going a little bit about this
5 later, we're going to need any information as to whether or
6 not different provisions are needed for small businesses.
7 And finally, any information that you would like to submit
8 to us on that will help us make the new rules easy to
9 follow and effective. And, thank you for your time.

10 MR. ZINK: Our next speaker is Dr. Bruce
11 Tompkin. Now while most of us were here because it's our
12 job, Bruce is retired. Bruce is retired as vice-president
13 of Product Safety for ConAgra Refrigerated Prepared Foods,
14 and Bruce has had a long and very successful and esteemed
15 career in food safety, food microbiology. His expertise is
16 internationally recognized. He got his Ph.D. from Ohio
17 State. We won't hold that against him, and he has spent
18 his entire career with a company that underwent a number of
19 name changes, proving that you can continually survive many
20 reorganizations. Beginning when it was called Swift and
21 Company, then Beatrice Refrigerated Foods, and Swift
22 Eckridge, and Armour Swift Eckridge.

23 Throughout all these years, Bruce saw the
24 arrival of listeria monocytogenes as a problem in ready-to-

1 eat meats, and he was a leader in how to deal with it. He
2 serves in numerous professional capacities. He is a member
3 of the International Commission on microbiological
4 specifications of foods which has published perhaps the
5 most lucid works on how to implement, process controls and
6 microbiological controls and microbial hazards. He's a
7 member of the National Advisory Committee on
8 microbiological criteria for foods. He's a member of the
9 Joint FAO/WHO Expert Consultation on microbiological risk
10 assessment, particularly listeria monocytogenes in ready-
11 to-eat foods, and salmonella in poultry and eggs. He's
12 authored almost a 185 research papers and reviews,
13 publications and presentations, chapters in more than 30
14 books.

15 So his experience is considerable, and this is
16 exactly the kind of person we like to hear from when they
17 can look back on their years of experience in the industry,
18 what they saw about good manufacturing practices, what
19 worked, what didn't, and where we ought to go for the
20 future. Bruce?

21 DR. TOMPKIN: Thank you, Don. I hope that
22 doesn't have to deduct that from my ten minutes. But it is
23 really a pleasure to be retired, if you haven't experienced
24 that yet.

1 The current GMPs are based on a long history of
2 learning what can go wrong, and then how to prevent similar
3 problems from occurring in the future. So, what we have is
4 a result of a lot of experience, an evolutionary process to
5 get to where we are today. The information currently in
6 the GMPs is comprehensive. It is still current, and I
7 don't think it needs major changes, but certainly it can be
8 modified to further clarify and improve. GMPs are very
9 important to the food industry. They provide the
10 foundation for industry's food safety control systems and
11 in particular, the Hassip systems, where that is
12 appropriate.

13 So we do use them, and it's very, very
14 important that they be sufficiently comprehensive that we
15 can draw from them. Picking up on what you said, Dr.
16 Williams, food safety really should be driven by
17 epidemiologic data that identify hazard food combinations.
18 And if you think back, what has happened since 1986 when
19 the last revision of the GMPs were revised, listeria
20 monocytogenes in ready-to-eat foods certainly comes to
21 mind, and the larger issue, perhaps in terms of recalls and
22 some other areas, is the undeclared allergens, and we will
23 be hearing about the allergen issue so I won't go into
24 that. But relative to getting at the science basis for the

1 food control systems and GMPs, there are a number of things
2 that we can draw upon. Well, for example, even since 1986,
3 FDA, USDA and other public health agencies have established
4 public health goals for healthy people 2000-2010.

5 So, we have specific public health goals for
6 which we are striving as a nation, and essentially the GMPs
7 are a foundation that's going to help us get there. And,
8 if there are weaknesses, we should be identifying those as
9 we move along. In 1999, Meade, et al., published its
10 document on the number of cases, hospitalizations and so on
11 and it was rather revealing that viruses really account for
12 67 percent of cases of food-borne illness in the U.S.
13 today, and bacteria 30 percent, and parasites three
14 percent. But that flip-flops when it comes to the public
15 health impact to the individuals involved. So that
16 actually bacteria account for 60 percent of the
17 hospitalizations and 72 percent of the deaths.

18 So I think it's that kind of information that
19 we can draw upon from CDC that could help provide guidance
20 as to where we need significant improvement.

21 Other sources of information are the Food Net,
22 EPI studies from CDC which are very important to us, and I
23 think that needs strengthening. Even the old MMWR annual
24 reports of disease allow us to track trends, as well as the

1 food net data. FDA and others do conduct product surveys
2 that's helpful information, and inspections, compliance,
3 and recalls are additional sources of information. These
4 various sources really are, should be used to better
5 understand the significance of chemical, physical and
6 biological hazards in our food supply. And this
7 information, this scientific-based information should be
8 used to monitor trends and assess whether the GMPs do need
9 modification.

10 The question could be asked then, are failures
11 in our food safety system due to something missing or that
12 is not clear in the current GMPs, or are they due to
13 improper implementation? I think that's a similar question
14 to what FDA has tried to address on its own. In going
15 through the GMPs, I do have one comment to make. The CDC
16 has a responsibility on an annual basis to list the
17 diseases that are food-borne diseases that are food-handler
18 origin, and it would be helpful to have a link to the CDC
19 website so that when we talk about diseases transmitted by
20 workers in the production facilities and so on, we'd know
21 specifically what CDC thinks is important at that point in
22 time.

23 Now, I think the real crux of this GMPs comes
24 to this one paragraph where it states that "if food is

1 adulterated, if it's been manufactured under such
2 conditions that it is unfit for food or the food has been
3 prepared, packed or held under unsanitary conditions
4 whereby it may have become contaminated with filth or
5 whereby it may have been rendered injurious to health."
6 That essentially sets forth the purpose for the GMPs, and
7 as I view it and I think others in industry would, the GMPs
8 essentially define the conditions then that are considered
9 acceptable or unacceptable and that are necessary for
10 producing, storing and transporting safe and wholesome
11 foods.

12 So, essentially it's the rules of the road and
13 it's very important from that perspective. But considering
14 the wide variety of foods, processes and establishments
15 that the GMPs that fall under FDA, the GMPs should be
16 broadly written, and not too prescriptive. And then it is
17 industry's responsibility to implement the GMPs to meet
18 their specific, unique circumstances. I think more
19 specific guidance can be developed for segments of the
20 industry where greater control is needed, and FDA has taken
21 that initiative for example, for the juice regulations, and
22 then for sprouts.

23 In concert with that, industry also has played
24 a role in providing specific guidance. For example, there

1 is a guidance document now that's been generated by the
2 smoked fish industry for control of listeria monocytogenes.

3 There also is a guidance document on how to control
4 listeria monocytogenes in processing environments where
5 ready-to-eat foods are exposed and subject to
6 contamination. Many of us have been through allergen-
7 control workshops that have been essentially developed and
8 sponsored by industry.

9 So, there are a number of activities that can
10 essentially be generated and used to highlight specific
11 problems and enhance control, essentially taking the GMPs
12 that are rather broad in nature and bringing them into
13 focus for those specific issues where additional help is
14 needed. And thinking through the GMPs, I believe that new
15 guidance for food operators is needed on how to think
16 through their operations and decide which hazards are
17 important for control. And I think the 1997 National
18 Advisory Committee on microbiological criteria for foods
19 document on Hassip does contain very good guidance on how
20 to conduct a hazard analysis, and I think it would be
21 helpful.

22 I don't want to put the idea of a regulation in
23 someone's mind, but I think that that material is well-
24 written and it could be modified and converted into a

1 thought process, a check list, however you want to do it,
2 that food operators could use to think through their GMPs.

3 What hazards are more likely to occur in their specific
4 operation and how, which GMPs deserve greater emphasis for
5 control of those specific hazards. I think that guidance
6 is currently missing and that could be helpful with regard
7 to the training aspect.

8 And finally, the GMPs that are adopted by
9 federal agencies should be compatible with a Codex general
10 principles of good hygiene practices adopted in 1997. And,
11 as is the case with the FDA GMP regulation, the Codex
12 document is very thin for their good hygiene practices, but
13 this document from Codex has not only the general
14 principles, but specific additional guidance documents for
15 specific segments of the food industry at the international
16 level.

17 So, we're all going in the same direction, but
18 it is very important for equivalency and world trade that
19 whatever FDA undertakes in terms of modification, that they
20 be in at least compatible with what we're working with at
21 the international level. I'd like to thank you.

22 DR. ZINK: I'd like to introduce our next
23 speaker. Terry Furlong is co-founder and chief operating
24 officer of the Food Allergy and Anaphylaxis Network and has

1 been with the organization since June, 1997. He's
2 responsible for FAAN's business and governmental affairs,
3 research and operation. He's been intimately involved in
4 the development and progress of the food allergen labeling
5 and Consumer Protection Act, changes to 25 state laws or
6 regulations relating to the availability of epinephrine
7 from emergency medical technicians, and is a FAAN's expert
8 on traveling with food allergies, especially on commercial
9 airlines.

10 Terry's research focus has been on the
11 epidemiology of food allergy and includes peer-reviewed
12 published studies on peanut and tree nut allergy including
13 reactions to peanuts and tree nuts in restaurants, schools
14 and airplanes. He sits on the anaphylaxis and adverse
15 reactions to food committees of both the American Academy
16 of Allergy, Asthma and Immunology and the American College
17 of Allergy, Asthma and Immunology. As co-founder of FAAN,
18 he has a personal interest in food allergy.

19 His youngest daughter was diagnosed with milk
20 and egg allergy as an infant, and I think that's certainly
21 enough to spur anybody into concern about food allergies.
22 Before joining FAAN, he spent eight years as a senior vice-
23 president of the American Trucking Association, 20 years
24 with Time-Life's book, music and video publishing

1 operation, and he has a Master's of Science degree in
2 business policy from Columbia University School of
3 Business. Terry?

4 MR. FURLONG: Thank you very much. First of
5 all, I'd just like to note that the food allergen labeling
6 and consumer protection act passed the House yesterday, so
7 we're very pleased with that, and if President Bush signs
8 it, it will become law effective January of 2006.

9 I'm going to briefly touch on today a little
10 bit of background on food allergy and then articulate what
11 our causes for concern are in the areas of undeclared
12 allergens, precautionary allergen statements, and rework.

13 About 11 million Americans are allergic to some
14 sort of food. The vast majority of them are fish or
15 shellfish and/or peanut and tree nut. Six and a half
16 million is a number that was just published this month in
17 the Journal of Allergy and Clinical Immunology. And peanut
18 allergy in children has doubled from 1997 to 2002. But the
19 buying behavior of many more millions are affected. All of
20 those children with peanut allergy have mothers and
21 fathers, aunts and uncles and grandparents and teachers and
22 childcare workers who are making buying decisions based
23 upon the needs of the food allergic child, so there's a big
24 leverage in this number. And as I'm sure you know, milk,

1 egg, wheat and soy are the other major allergens.

2 The concerns we have in this area that in the
3 incidence of food allergy may not yet have peaked. That
4 trace amount of allergens can cause fatal reactions.

5 There's no cure for food allergy. Strict avoidance
6 of an allergen is the only way to prevent a reaction.
7 Severe allergic reactions to food result in about 30,000
8 trips to the emergency department every year, and about 200
9 deaths in the U.S. In the health and safety of food-
10 allergic individuals depends upon clear, accurate and
11 reliable food labels. In a survey we did last year of
12 almost 700 attendees at our conferences across the country,
13 we asked them "have you ever called a food manufacturer for
14 more information about a product's ingredients?" And 75
15 percent of them reported that they had. We think that
16 suggests that there's either not enough information on the
17 label or not the right kinds of information, or it's not
18 clear enough.

19 Food allergy is clearly a significant food
20 safety and public health issue. People's lives depend upon
21 knowing with certainty what is in a food item. Some
22 companies have embraced the issue, others have ignored it.

23 Compliance can't be optional. In the 1999 recalls, 35
24 percent were due to undeclared allergens. That's a

1 staggering figure. They were caused by three principle
2 factors. Ingredients statement omissions and errors,
3 cross-contact from shared equipment, or human error. The
4 area of undeclared allergens FAAN members regularly call in
5 to food manufacturers and the FDA to report reactions.
6 Dozens and dozes of products that have been suspected of
7 causing allergic reactions due to undeclared allergens have
8 been confirmed in tests by the food allergen research and
9 resource program at the University of Nebraska.

10 I'm going to run through a couple of cases
11 briefly just to illustrate the kinds of things that these
12 folks are up against. A FAAN member reported that his
13 daughter had had a reaction to a cookie. The manufacturer
14 told him the item was made on shared equipment and the
15 company acknowledged that cross-contact was the problem.
16 Another member told us that her 16-month old son had a
17 reaction to a frozen fudge product. The company told her
18 that there was a possibility it contained milk because it
19 was made on the same equipment as milk products and
20 employees aren't careful these days.

21 Another FAAN member reported a product,
22 indicating that it contained traces of peanuts. Her tree
23 nut allergic daughter had had a reaction. The company told
24 her that the product was made on the same line with

1 walnuts, not peanuts, and there was no indication that it
2 may contain walnuts. In this case, a FAAN member purchased
3 a half-gallon of ice cream. The label stated that it
4 contains milk. While she was eating it, ran into a sliver
5 of nut. The company informed her that all their ice creams
6 are made on shared equipment, but no nut warning was given.

7 On the precautionary allergen statement front,
8 the allergen advisory or "may-contain" statements were
9 developed by the food industry as a way to better
10 communicate additional allergen information to those with
11 food allergies, and we applaud those efforts. The
12 statements are voluntary. There is no standardization of
13 messages, no rules for what they mean, and no rules for
14 when they can or should be used. There's a 1996 FDA letter
15 that says that "may-contain" statements cannot be used in
16 place of good manufacturing practices, and we're afraid
17 that that's where a lot of them have gone.

18 There's a tremendous proliferation of the types
19 of messages and the numbers of products that contain them.

20 About a year and a half ago, one of our staffers went to a
21 local super market in Virginia and sampled precautionary
22 allergen statements in four product categories: candy,
23 cookies and crackers, snack foods and other cereal, bread
24 and baked goods, et cetera. She found 28 different

1 precautionary allergen statements on the packages. Some
2 companies use them, some don't. Some of them use them
3 sparingly. Others put them on all of their products.
4 Consumers are confused, and forced to spend more time
5 decoding the messages.

6 What do all of these statements mean? I'll
7 give you some examples. One FAAN member asks "Is there a
8 big difference between may contain traces of peanuts and
9 manufactured in a facility that uses peanuts." How is a
10 consumer to know? Should we follow the same precautions
11 for both of these warnings? After acknowledging cross-
12 contact as a result of an allergic reaction, a company told
13 our member that when they order new packaging, they would
14 add a warning to the label. However, it might take a few
15 weeks.

16 In another, a FAAN member reported that a
17 chocolate bunny that she had purchased listed no peanut, no
18 tree nut ingredients and featured no allergy warning.
19 Identical products in the store had "may contain peanuts"
20 on the label. The manufacturer said that all the bunnies
21 made on the same equipment, were made on the same
22 equipment, and all should have had the same warning. This
23 is consumer confusion.

24 Consumers often don't read the ingredients

1 statement if a product has a precautionary allergen
2 statement. So, if it says one thing, it needs to be
3 consistent. Sometimes they're inconsistent, thereby
4 increasing a risk of a reaction. Examples are that some
5 companies think that peanuts are the only allergen that
6 warrants advisory labeling. They have "contains peanuts"
7 statements even though it also contains other major
8 allergens. And some companies think that peanut and tree
9 nuts are interchangeable. One company that put "contain
10 traces of peanuts" on the label of a product that is
11 manufactured on equipment that is shared with walnut
12 containing food.

13 But the ultimate we think is this one. We've
14 paraphrased it for brevity here, but it says "may contain
15 peanuts and other allergens not listed on the label."
16 Anybody have a guess at what's in there? We sure don't.

17 Rework is our other area of concern. There are
18 no regulations regarding rework in allergens. It's
19 mentioned in the compliance guidelines. But the result of
20 not taking food allergen control seriously or keeping like
21 into like when handling rework can be deadly. A 21-year
22 old boy with a known allergy to peanut died after ingesting
23 chocolate chip cookies. Peanuts were not listed in the
24 ingredients nor was there a precautionary statement.

1 Testing after the fact revealed three thousand parts per
2 million.

3 A prominent allergist with a known peanut
4 allergy nearly died after ingesting ginger snap cookies.
5 The product had undeclared peanuts from rework. If it
6 wasn't for his training and his ability to recognize his
7 own symptoms and his access to epinephrine, he would not
8 have survived.

9 So, in conclusion, we believe that food
10 allergic consumers depend on the FDA to protect them.
11 Their lives depend upon accurate, clear and reliable
12 labeling. The agency must take the lead in food allergen
13 controls, especially as it relates to labeling and good
14 manufacturing practices. We heard some discussion the
15 other day about guidances versus regulations. We think
16 guidances are merely suggestions, and therefore, optional.
17 Regulations include lots of "shalls", and consumers lives
18 are dependent upon compliance. We need the "shalls."

19 In an ideal world we would have manufacturers
20 using separate equipment for allergens and non-allergen
21 containing product, but that's not the reality. We think
22 FDA must provide regulations regarding GMPs, rework and
23 labeling so that all companies that are doing the best they
24 can regarding separating, cleaning, packaging and labeling

1 of allergens.

2 Food allergen control measures should be part
3 of the Hassip plan of all companies who use allergens, not
4 just the few industry leaders who get it. Consumers can't
5 manager their food allergies alone. They need the help of
6 the FDA and the food industry. They must have accurate
7 information on the label and proper food allergen
8 management at the plant in order to avoid a reaction.
9 Lives depend on it. Thank you very much.

10 DR. ZINK: I'd like to introduce our next
11 speaker, Marlana Bordson. Marlana has been with the
12 Illinois Department of Public Health, Division of Food,
13 Drugs and Dairies for 32 years in a variety of positions in
14 food and dairy sanitation. She currently serves as
15 Division Chief and Acting Dairy Program Manager.

16 Prior to accepting the position of Dairy
17 Program Manager, she served as Regional Supervisor for the
18 Division in the Champaign regional office, covering sixteen
19 counties in East Central Illinois. During that time, she
20 was certified by the FDA as a Retail Food Evaluation
21 Officer. She serves as Chairman of the National Conference
22 on Interstate Milk Shipments Executive Board. As a member
23 of the National Conference on Interstate Milk Shipments FDA
24 Liaison Committee, the Halling Practices Committee and the

1 Program Committee.

2 Currently, she serves on the Illinois
3 Department of Professional Regulation, Board of
4 Environmental Health Practitioners, the Illinois Department
5 of Agriculture, Yonees Disease Advisory Committee, the
6 Illinois Food and Water Security Work Group, and as an
7 advisory member of the Illinois Milk Producers Association.

8 Marlena?

9 MS. BORDSON: Thank you. I appreciate the
10 opportunity to present comments on behalf of the state
11 regulatory agency on the issue of updating the food current
12 good manufacturing practices.

13 Our agency participates fully with the Food and
14 Drug Administration in the conduct of regulatory
15 inspections and related activities such as enforcement and
16 sampling under our contract for food processing and
17 warehousing inspections, and under various partnership
18 agreements. Illinois has adopted enabling legislation and
19 rules patterned after the Federal Food, Drug and Cosmetic
20 Act and the current good manufacturing practices and
21 utilized these as the basis for our direct inspection and
22 enforcement activities.

23 We believe, in general, that the good
24 manufacturing practices have been very good in providing a

1 framework for safe and sanitary manufacturing, processing,
2 and holding of food for human consumption. These
3 regulations have provided a strong foundation from which
4 food category-specific regulations, compliance policy
5 guides, passive regulations and industry-quality programs
6 could be implemented. However, there are improvements that
7 should be considered in order to provide greater assurance
8 of food safety. When considering any changes, it is
9 important to remember that the success of these current
10 good manufacturing practices has been their applicability
11 to many different types of food industries.

12 We recommend that the regulations remain basic
13 and to the point. In order to more effectively control the
14 three types of hazards identified in this public notice,
15 physical, chemical and biological, the regulations should
16 be more specific in the statement of the hazards in
17 connection with the regulation or recommendations. For
18 example, under the section on personnel, controls for
19 physical, chemical and biological hazards are intermingled.

20 Inspections staff prefers to evaluate compliance with
21 rules in broad categories such as personnel, building and
22 facilities, equipment for example. But we recommend that
23 within each of the categories, the regulations be arranged
24 to group control requirements or recommendations for like

1 hazards together.

2 In reviewing the questions posed in the notice
3 for these public meetings, I was struck in particular by
4 the request for recommendations for how the effectiveness
5 of preventive controls be most accurately measured. I
6 reflected on the struggle to document and measure for our
7 own agency how effective our programs have been. How do we
8 measure what we have prevented? Is a control for metal
9 objects in the finished product best measured by how many
10 pieces of metal are found or by a reduction in the number
11 of consumer complaints on pieces of metal in finished
12 products? Should we look at large populations over several
13 years such as the healthy people 2010 objectives for
14 reducing specific food borne illnesses, or do we measure
15 the reduction in numbers of violations in broad categories
16 that are attributable to factors causing food borne
17 illness?

18 In comparing CDC data to our own data collected
19 in Illinois, we see that the factors contributing to food
20 borne illness replicate the five leading causes identified
21 by CDC: improper holding temperatures, poor personal
22 hygiene, contaminated equipment, foods from unsafe sources,
23 and improper cooking temperatures. In the years 2000 to
24 2003, Illinois factors varied slightly by adding ill food

1 handlers to the list instead of foods from unsafe sources.

2 However, each of these factors can be directly attributed
3 to some failure to control a biological hazard. Similar
4 reporting systems would need to be utilized to allow us to
5 look at large numbers of reportable illness or injury
6 attributed to physical or chemical hazards.

7 Another question dealt with controlling the
8 presence of undeclared allergens in food. The principle
9 contributors to the presence of undeclared allergens in
10 food may be as simple as a lack of understanding of the
11 serious nature of allergenic reactions to as complicated as
12 preventing product carryover in large multi-product
13 production facilities. Both labeling errors and cross-
14 contamination contribute.

15 Frequently such reactions occur because the
16 presence of the allergenic substances in the food is not
17 declared on the food label. Allergens may be
18 unintentionally added to food as a result of practices such
19 as improper rework addition, product carryover due to use
20 of common equipment, and production sequencing or the
21 presence of allergenic product above exposed product lines.

22 Such practices with respect to allergenic substances may
23 be unsanitary conditions that may render the food injurious
24 to health and adulterate the product.

1 However, the current GMPs do not adequately
2 address allergen control, although control measures could
3 be inferred for the controls for physical, chemical or
4 biological hazards.

5 The section of education and training of
6 employees only includes the dangers of poor personal
7 hygiene and improper food handling techniques. It should
8 also include education and training in all aspects of
9 hazard control including allergen control.

10 I recommend that FDA look to existing quality
11 systems that have modernized in recent years including the
12 pasteurized milk ordinance, the food code and the shellfish
13 ordinance. These programs have had the benefit of the
14 involvement of individuals from all sectors, regulatory,
15 industry and consumers. In recent years, greater efforts
16 have been made to assure that changes to provisions of the
17 model ordinances are science-based and are implemented
18 under proper legal authority.

19 As stated previously, any revision to the
20 current good manufacturing practices should take into
21 consideration the variations within the food industry and
22 provide broad recommendation for those areas that can be
23 handled generically. However, there should be different
24 sets of preventive controls for identifiable segments of

1 the food industry. With particular reference to
2 temperatures, the temperatures for cold and hot food
3 storage in sub-part E, production and process control,
4 Section 110, point ADB3 should be changed to reflect
5 temperatures adopted by the conference for food protection
6 of 41 degrees Fahrenheit and 135 degrees Fahrenheit in the
7 food code. Sufficient time for industry-wide correction of
8 temperature control equipment and facilities must be taken
9 into consideration.

10 In addition, in Section 110, ADB4, the term
11 "adequate" is used to evaluate measures such as
12 sterilization, irradiating, pasteurization, et cetera. The
13 definition of adequate is not well defined. This poor
14 definition remains one of the biggest stumbling blocks to
15 evaluating compliance with measures and this is a quote
16 "that are taken to destroy or prevent the growth of
17 undesirable microorganisms, particularly those of public
18 health significance." It would be preferable to use terms
19 such as measures that can be demonstrated, validated or
20 documented.

21 Also noted in the questions for consideration
22 were a number of measures, procedures and programs that
23 could be used to ensure that preventative controls are
24 carried out adequately. Without listing each item

1 individually, we recommend that all of these be required
2 items that a plant or warehouse must abide by as part of a
3 current GMP program. Although small or basic operations
4 may not have a sophisticated training program, they
5 nevertheless must be responsible for the training of their
6 employees. Likewise, written records may be on a clipboard
7 or in a computer, but records must be maintained.
8 Validation of control measures as previously mentioned,
9 must be routinely documented.

10 Finally, inadequate attention is given to the
11 prevention of all types of hazards in the warehousing and
12 transportation of foods. Circumstances that are unique to
13 warehousing and transportation are not addressed at all,
14 are frequently neglected, and are critical to the
15 protection of the food supply.

16 Thank you for the opportunity to comment.

17 DR. ZINK: Our next speaker, Mr. Brian
18 Hendrickson, is with the Food and Drug Administration,
19 Office of Regulatory Affairs. Brian is one of our national
20 food experts in the Division of Field Investigations. As
21 such, he's regarded as a national authority in food
22 inspections. He conducts inspections related to the most
23 complex, controversial and precedent setting scientific and
24 regulatory problems, both nationally and internationally.

1 He has been involved in developing agency policy and in
2 developing and presenting national and international
3 training programs to FDA, state and foreign governments in
4 the area of low acid canned foods, acidified foods and
5 packaging. He has 32 years experience as an FDA field
6 investigator. He holds a Bachelor's Degree in Food Science
7 and Technology from Oregon State. He's a member of IFT and
8 the Institute for Thermal Processing Specialist in the
9 North Central Association of Food and Drug Officials.
10 Brian?

11 MR. HENDRICKSON: Good afternoon. As the last
12 speaker, a lot of my speech has already been presented, but
13 it shows that really, we're in sync, which is very
14 interesting, but I didn't have the privilege of seeing
15 their speeches.

16 As a member of FDA's Division of Field
17 Investigations, Office of Regulatory Affairs, I am going to
18 present the following comments from a regulator's
19 perspective because I'm really out there in the field doing
20 inspections, doing GMP audits, training other people in the
21 field to do this activity, and also we do a lot of
22 classroom training, so we're really using the food GMP, and
23 what I'm going to do is I'm going to talk a little bit
24 about the updating of this very important regulation.

1 Good sanitation is mandatory for all foods.
2 Section 402A4 of the Food, Drug and Cosmetic Act deems food
3 adulterated if it has been prepared, packed or held under
4 insanitary conditions. Those conditions or practices that
5 are necessary to produce a food that's not adulterated are
6 outlined by the food GMP. For years FDA has been
7 regulating the food industry under this GMP, 21CFR as we
8 know it now as Part 110. It goes way back. I came in the
9 FDA in 1972 and at that time the food GMP was known as
10 21CFR, Part 128. And I think it was the late 1960's when
11 it first became effective. So, we've been using it for
12 over 30 years, long time. However, the agency has not been
13 completely successful in developing a culture whereby food
14 processors take a, assume the role of operative controls in
15 assuring sanitation within their plants.

16 The statistics relating to the incidence of
17 insanitation cited in the preamble to the seafood Hassip
18 regulation, and observations from USDA's Hassip rules for
19 beef and poultry, clearly demonstrate that such a culture
20 was not in place in 1995, and this is just a year or so
21 before these rules became effective. Further, the
22 requirement of standard sanitation operating procedures,
23 SSOPs, sanitation monitoring and record keeping in the more
24 recent juice Hassip regulation further highlights the

1 significant need to motivate a portion of the food industry
2 to comply with sanitation requirements. As previously
3 mentioned by Dr. Williams, an FDA CFSAN division of market
4 studies examination of food recalls from 1999 to 2002,
5 found that a majority of the recalls were related to a good
6 manufacturing practice problem.

7 Some of the good manufacturing practice issues
8 outlined in the study were as follows and I'll just briefly
9 just mention them again, and they've already been mentioned
10 before but, incorrect labeling and we're talking about
11 allergens here as a big problem; ineffective training, and
12 this is really been stressed before in presentations here;
13 product cross-contamination; lack of routine maintenance;
14 poor equipment and plant design; lack of temperature
15 control; and ineffective employee hygiene. All of which,
16 with the exception of labeling, are addressed in the food
17 GMP. Although the number of food recalls relating to
18 sanitation seems high, it makes sense as FDA's own database
19 shows, that the top 30 food inspections observations made
20 by FDA investigators during inspections, relate exactly to
21 these types of GMP deficiencies and more.

22 Taking a look at the GMPs, the GMP regulation
23 for food is long overdue. FDA, consumers, the regulated
24 food industry and other interested parties need to take the

1 time to evaluate the these regulations and make suggestions
2 for revisions. If successful, these revisions would help
3 FDA assure that firms take full responsibility for
4 sanitation in their plants, which, of course, relates to
5 the production of safe and wholesome food. Revision of the
6 current regulation should attempt to strengthen the current
7 requirements in the following ways.

8 Requiring specific daily sanitation regimens
9 that incorporate features such as monitoring, corrective
10 action and record keeping, to help the processor track
11 sanitation in their plants. Statistics from the seafood
12 Hassip program as it relates to sanitation have shown that
13 this type of requirement has helped with compliance. For
14 example, the seafood Hassip regulation, when if first
15 became effective in December, 1997, 1998 was the very first
16 year that it was really used by the food industry and FDA
17 started to do inspections, GMP inspections to enforce this
18 regulation, Part 123.

19 In 1998, the percent of firms that had adequate
20 sanitation controls, including GMPs, sanitation, and record
21 keeping was 21 percent. While in 2003 or five years later,
22 after being inspected by FDA, by FDA audits over those
23 years, it was 54 percent, an over 100 percent improvement
24 in five years.

1 Okay, the next point I want to make is
2 requiring specific records for verification activities such
3 as calibration of monitoring equipment to ensure that
4 accurate instruments are used to measure and control
5 process parameters. Requiring documented validation for
6 equipment design. Process establishment and process
7 delivery to ensure that the process is designed and
8 delivered to control or eliminate specific targeted
9 hazards.

10 The next point: addressing more stringently the
11 training requirements for food plant operators as well as
12 employees, and documentation of that training to ensure
13 that food plan operators and employees understand the
14 responsibilities for producing safe food products.

15 The next point: defining allergens and
16 requiring monitoring and record keeping to assure the
17 products are properly labeled. And in addition, defining
18 additional terms used the food industry such as
19 pasteurization, for example. Pasteurization, we think of
20 pasteurization, we think of milk processing for a certain
21 number of seconds, holding food at a certain temperature
22 has been pretty well defined, but really, many products are
23 pasteurized. Crab is pasteurized, acidified vegetables are
24 pasteurized. Acid fruits are pasteurized. Pasteurization

1 can include high intensity light, and new processing
2 techniques such as high pressure processing, what exactly
3 is pasteurization? It needs definition.

4 The next point here is requiring each food
5 processor to determine hazards associated with their
6 products and manufacturing processes in controlling those
7 hazards throughout the process.

8 These are just a few items that not only I feel
9 that needs addressing, but it's a kind of collective
10 opinion of the other national food experts that work for
11 the Division of Field Investigations. Today we hope to
12 elicit responses from you and other suggestions to help FDA
13 foster a climate of and a commitment to good manufacturing
14 practices that may well have been lacking in a significant
15 portion of the food industry. Thank you for your time.

16 DR. ZINK: What I'd like to do now is, you've
17 heard the invited speakers. I'd like to open it up for a
18 period of questions. We will encourage anyone in the
19 audience to ask whatever questions might be on your mind.
20 We'll do our best to deal with it. If you would like to
21 direct it to specifically one of the speakers, please say
22 so. So, if there are any questions, please come to the
23 microphone and I ask you again, to identify yourself and
24 your affiliation. Not everybody at once now.

1 MR. FOWERS: I'm Mike Fowers, coordinator of
2 product quality, Amalgamated Sugar Company. The question I
3 have is with Dr. Tompkin. You mentioned that he was
4 involved with the role with FDA in trade agreements. I'm
5 curious as how much is the FDA involved with those trade
6 agreement regulations and, like CAFTA, and how will the FDA
7 evaluate if the importers are complying with the GMPs?

8 DR. WILLIAMS: I heard a 2-part question, and I
9 want to make sure I understand. First of all, the second
10 one, let me start with the second one, because I think we
11 got that one before. You asked how will we ensure that
12 manufacturers from overseas that are exporting to this
13 country comply with this? That was the second part of the
14 question? The first part was about trade agreements, and I
15 am not involved in those trade agreements. Nega, would you
16 like to, because you've been so, anything you want to say
17 with that? Our regulation right now is just focused on,
18 first of all, let's do first things first. First of all,
19 we have to see what we're going to do with this regulation.
20 And then in terms of enforcement, we're going to enforce
21 this regulation just like we enforce all our regulations on
22 imported foods. I don't think any changes there, Don, do
23 you?

24 MR. ZINK: Well, one thing we recognized in

1 looking at this is, and one of the reasons Dr. Crawford
2 cited it in his introduction is 20 years ago it was a
3 different story than it is now. We have a very much more
4 global food supply now than we did say 20 years ago. I
5 imagine myself being overseas, either working for a foreign
6 government or a foreign manufacturer, looking at 21CFR,
7 Part 110 trying to decide what it is that's required. And
8 certainly, words like adequate and things like that might
9 be confusing to them. The very broad nature of that which
10 is important for general applicability of the regulations,
11 you know, is an issue, and so, clarification of these
12 regulations, yet while keeping them broadly applicable is
13 one of the challenges and perhaps, you know, guidance
14 documents to make it more clear to all of our trading
15 partners what's required. We're in a different world today
16 than we were when those were first written.

17 MR. RUSHING: John Rushing. I'm from North
18 Carolina State University in Raleigh. One of the things
19 that concerns me a little bit is the state intent of the
20 GMPs is to be able to regulate other 402A4 of the
21 regulation, I mean of the statute, and I guess my concern
22 is I hear from more and more regulators that you cannot
23 really follow up very well with violations of 402A4 based
24 on the GMPs, and I'm wondering if the new GMPs will be able

1 to correct that or will that just come as a ruling from
2 counsel, or will it develop into the same concerns we have
3 now, or what do you think's going to happen there?

4 DR. ZINK: I smile because we've heard this
5 before. It got so bad at one point that we've had to
6 declare a moratorium on this debate within our working
7 group. That are some that will tell you that it's
8 difficult to enforce, and there are some that will tell you
9 it's enforced all the time. And both are true. We take
10 enforcement action under 402A4 all the time and for GMP
11 violations. I mean, not a week goes by that we probably
12 couldn't cite a case history where we do. However, if you
13 speak, you know, from a lawyer's perspective perhaps,
14 lawyers would love something, you know, stronger and more
15 specific. But I believe, you know, we can enforce 402A4
16 and we do it all the time.

17 DR. WILLIAMS: I would just add that we are
18 following up on that very question, but thank you for
19 asking it.

20 DR. ZINK: Any more questions. Bruce, did you
21 have anything?

22 MR. TOMPKIN: I had just one comment relative
23 to international situations. A number of my colleagues in
24 other countries wonder what is GMP is. They think only of

1 good hygiene practices or GHP and they continually ask me
2 what is a GMP? And if you put the Codex general
3 principles, the outline, create an outline for the
4 components, along side the FDA GMPs, they are basically
5 identical. The words are different but all the parts are
6 the same. And then FDA has added some portion onto it with
7 regard to process control. There are some differences that
8 way. But, some clarification is from an international
9 perspective, and I don't know how you do it in a federal
10 register, but it would be to actually for our foreign
11 trading partners, explained how do the GMPs, U.S. GMPs fit
12 in to the international concept of GHPs.

13 DR. ZINK: Any more questions? Yes?

14 MR. RAY: My name is David Ray with NewlyWeds
15 Foods. I'm interested if the agency has any plan to set up
16 the minimis or minimums for allergens in terms of either
17 parts per million or some level so we can set up a
18 validation studies and so forth?

19 DR. ZINK: I have not been an active part of
20 the group working on food allergens, and so I really can't
21 speak to that directly. I don't know, is there any, Fay,
22 do any of you, Nega, have you been more involved with it?
23 This is Nega Beru, from the Office of Plant of Dairy Foods.

24 MR. BERU: Yes, my name is Nega Beru, Division

1 of Plant Product Safety. There is some work to try and
2 look at what is a threshold that elicits and allergenic
3 response, and there's some studies being done. Studies,
4 reviews of the literature, but I think we're quite a ways
5 from declaring that level at which, because science is just
6 not there, what is the minimum amount that elicits an
7 allergenic response. We're just not there.

8 MR. RAY: Well, just to follow up on that.
9 We'd be very interested in having that based on science and
10 having a level at which we can then track to, because right
11 now we're, of course, making our own decisions and driving
12 it down to irreducible minimums, but the cost certainly is
13 a factor there, so, anything you all could do to help out
14 there would be helpful.

15 DR. ZINK: We certainly share the desire to
16 have it science-based.

17 MR. FURLONG: May I make a comment on that.
18 There are some studies under way to look at that very
19 issue. But they keep coming up with people who are ever
20 more sensitive and that's the problem. There is no
21 completed study yet that is defined with the minimum
22 elicitation doses for any of the major allergens at this
23 point.

24 DR. ZINK: Anyone else that would like to offer

1 a question? If not, what I'll do is, we'll adjourn here
2 for, let's say, what, oh, another one. Oh, in the back?
3 Can you come to the microphone?

4 MR. SONI: Sure. I represent Solo Cup Company
5 and we make packaging items --

6 DR. ZINK: Okay, and your name?

7 MR. SONI: My name is Hari Soni.

8 DR. ZINK: Okay.

9 MR. SONI: And, our customers sometimes expect
10 us to meet the same requirements like a food manufacturer.

11 Is the GMP going to address the needs of packaging
12 industry stuff?

13 DR. ZINK: The GMPs don't explicitly address a
14 manufacturer who is, say, producing packaging materials,
15 although I guess you would expect those materials to be
16 handled in a hygienic manner, in a way that they don't
17 contribute to the adulteration of foods. I don't believe
18 we've extended them to, we haven't them to actual
19 regulation or inspections of packaging producers. Brian,
20 do you recall any time in which investigations or
21 inspections are carried back to the packaging supplier
22 itself?

23 MR. HENDRICKSON: No, none. No, I haven't. I
24 don't think there's no regulation that goes back.

1 DR. ZINK: Yes, I think we've kind of put it on
2 the manufacturer to deal with their suppliers and ensure
3 that their supplier is delivering them packaging that
4 complies with the regulations and is handled in a sanitary
5 manner. Otherwise, it's that manufacturer that's got the
6 problem. Okay?

7 MR. SONI: Okay, thank you.

8 DR. ZINK: Okay, we have some more questions?

9 MR. REEGERS: Yes, Arnold Reegers, Step and
10 Company. To follow up on the packaging question, will the
11 GMPs then comply or apply to situations where food
12 producers say order chemicals from chemical companies that
13 would then enter the food chain. And I'm thinking of, say,
14 as a for instance, surfactose.

15 DR. ZINK: Yes, I mean, I think we would, you
16 know, if you'd like to make a written comment or suggestion
17 of how we could or should incorporate that, we'd sure like
18 to see it. Certainly, the GMPs would apply to any
19 situation in the plant where a chemical could, you know, be
20 an adulterant of the food product. Anymore questions?

21 MS. BLAIR: Betsy Blair with AIB International.

22 Back to the comment about international perspective. We
23 have an office in the UK and we do U.S.-style inspections
24 in Europe, and one thing that we've seen is they're much

1 more interested in paperwork. You may be familiar with the
2 BRC audit, the registration tripod. It's where you spend
3 maybe a day in a fifteen-line plant and you'll spend six to
4 seven hours looking at documentation and maybe an hour in
5 the plant, and that's good enough for a legal defense. And
6 coming from our background, where we've had enforcement of
7 our May clause for quite a long time and it's expanded as
8 time has gone on, it's given us a lot different perspective
9 over there as, okay, we're going to come in and we're going
10 to spend time in the plant, and if you've done any
11 inspections outside the U.S., it can be a little startling
12 sometimes. So, even though the legislation is the same, I
13 think the perspective of how they enforce it, you know, we
14 have our May clause, Canada has it, but over there it's
15 more due diligence defense. I've got truckloads of
16 paperwork, you shouldn't prosecute me, so, something to
17 keep in mind if you're going to look at expanding into
18 quality systems and things like that.

19 DR. ZINK: I don't think our philosophy will
20 change and that whatever you do in terms of paperwork, you
21 know, when you walk into the production area, it has got to
22 be a sanitary environment and they've to be producing food
23 that's not adulterated, irregardless of the paperwork they
24 may have to the contrary.

1 Further questions? What we'll do is let's take
2 a 10 minute break. Let's say we'll convene back here in 20
3 minutes before the hour, and at that time we'll open it up
4 for public comment and we have some other small business-
5 related presentations for you as well. Thank you very
6 much.

7 (A short recess was taken.)

8 DR. ZINK: Come in and take a seat. We have
9 two more brief presentations before the public comment
10 period. I'd like to introduce to you Marie Falcone. Marie
11 is the Regional Small Business Representative for the FDA's
12 15-state central region. Before that, for five years she
13 ran FDA's southwest region, Industry Outreach program
14 headquartered in Dallas, Texas, and she draws on her career
15 knowledge and experience as an FDA investigator and
16 investigation supervisor to assist those regulated by FDA
17 in understanding and complying with FDA requirements. Ms.
18 Falcone has received several FDA commendable service
19 awards, and the FDA Award of Merit for leadership in
20 promoting FDA's mission. Marie?

21 MS. FALCONE: Thank you, Dr. Zink, and hello
22 everybody. It's a pleasure for me to participate in this
23 meeting because it is the FDA's regional small business
24 representative's job to help implement the provisions of

1 the Regulatory Flexibility Act, which specifies procedures
2 for regulatory and informational requirements to ensure
3 that special needs of small businesses are considered.
4 Some of the Act's goals are: to improve the relationship
5 between government and small business, and by the way,
6 could you just show me by raising your hand, if you
7 consider yourself a small business.

8 So, there are some of you here. I'm very happy
9 to see that you're here, and I hope that more find out
10 about this GMP revision process. Another goal is to
11 encourage small businesses to participate in the agency's
12 decision-making process; to provide small business with
13 easier access to all levels of the agency; to provide
14 regulatory options which are least costly to small
15 business; and to help small business understand and comply
16 with FDA regulations.

17 To this end, the FDA regional small business
18 representatives assist entrepreneurs, consultants, owners,
19 operators and employees to understand FDA requirements. We
20 answer questions, provide guidance and explain the
21 intricacies of dealing with the FDA. When new regulations
22 issue, we contribute to the general FDA effort to respond
23 to questions about them.

24 We make referrals to other FDA offices for

1 those inquiries which require more technical expertise and
2 we work in conjunction with the small business outreach and
3 assistance offices of the FDA centers and the offices of
4 the Commissioner to smooth the regulatory pathway for small
5 business.

6 How many of you knew that FDA had small
7 business representatives before today? Well, that's good.

8 Okay, but that's not even half. The information on us,
9 small business representatives, is in the brochures that
10 were, that you picked up as you came in, contact
11 information about us and it's also on the FDA website at
12 www.fda.gov and on the industry activities page.

13 In preparation for this series of meetings, we
14 assisted the FDA center for food safety and applied
15 nutrition in outreach to small businesses to make them
16 aware of the opportunity to either attend the public
17 meetings and voice their concerns or to submit written
18 comments to the FDA either individually or in conjunction
19 with their associates, and I'm happy to say that at the
20 last meeting at College Park, I was talking to a
21 representative from Rutgers, and she said she's going to
22 get together with some of the small business outreach
23 groups in the area and maybe talk about making come
24 comments, so I was really happy about that. And FDA does

1 need to hear the concerns of small businesses, and the next
2 speaker, Dr. Nardinelli, will explain a lot more about how
3 to be effective in doing that.

4 We SBR's hear the concerns of small businesses
5 and hear the questions on a daily basis. About 40 percent
6 of the inquiries I receive are in the food area. And many
7 callers seek information on what to do with regard to food
8 manufacturing requirements on issues that are not addressed
9 in the current GMP. They ask if shelf life studies must be
10 done and whether an expiration date or use-by date must be
11 on the food package. They ask about standards and test
12 methods, how often and how much to clean their equipment,
13 how to assure their suppliers provide compliant ingredients
14 and packaging. They ask how they can select safe food
15 contact surface materials, and their concerns range from
16 tamper-evident packaging to employee health certificates.
17 They ask when they will be inspected and what records must
18 be kept, and whether the records of lot numbers are
19 required. They ask what the acceptable chlorine limits are
20 in sprout washes, and what kind of processing is necessary
21 for bottled ice tea or salsa. They want to know whether
22 food manufacturing equipment must have installation,
23 operation and performance qualification, how GMPs apply to
24 commercial kitchens used by a variety of small

1 manufacturers, whether they can produce food for commercial
2 distribution in their homes, whether a specific cleaning
3 compound is acceptable on a food contact surface. They
4 want to know where they can find reliable testing
5 laboratories for their products.

6 While the current GMP was written in general
7 terms so it remains a flexible standard as technology
8 changes, the broadness of its language at times creates
9 special problems for small businesses, because now there
10 are more questions on how to comply, and the need for
11 investigation and research by small businesses to locate
12 information in order to comply. Small businesses in
13 particular may not have the time or money to do this
14 research. And here's just one example: in the 21CFR,
15 110.40 Equipment and Utensils, it mandates that the design,
16 construction and use of equipment and utensils shall
17 preclude adulteration of food.

18 It also states they shall be made of non-toxic
19 materials. 21CFR, 110.80 states that appropriate quality
20 control operation shall be employed to ensure that food
21 packaging materials are safe and suitable. The indirect
22 additive regulations which are separate from the GMPs and
23 the FDA food contact notification website exist, and you
24 can get them, but they do not together, provide a usable,

1 well organized listing or reference for small businesses to
2 select food contact materials with competence. They are
3 compliant with FDA requirements and do not present
4 potential long-term hazards through migration of chemicals
5 into the food supply.

6 Food packaging has changed dramatically in the
7 past 20 years. Think of how many food products now that
8 are packaged in plastics and polymers from dressings and
9 sauces to acid fruit drinks that were not packaged that way
10 20 years ago. In the 12 years I have dealt with concerns
11 of small businesses, my impression is that they could
12 benefit from a review of 110 as well as how FDA organizes
13 and presents information needed to comply with the
14 generalities of 110 to the goal of developing a more
15 assessable, specific, understandable and integrated system
16 of requirements and supporting information in order,
17 ultimately, to reduce health risks in food supply. FDA has
18 shown in many arenas that it's capable of this kind of
19 activity, and I'm to meet specific needs of the regulatory
20 community for information.

21 The steps taken have resulted in smoothing the
22 pathway to compliance while eliminating the need for
23 redundant research by businesses. People have mentioned
24 the food code and it actually, the food code is for retail

1 food service sanitation and it actually does contain
2 specific and understandable information, for example, on
3 food contact surfaces.

4 21CFR, 110.110 immediately following the food
5 GMP addresses defect action levels, or those low levels of
6 natural or unavoidable food defects that are not hazardous
7 to health, and in another area of FDA called the Center for
8 Drug Evaluation and Research, they have what's called the
9 Post-Approval Changes Program, and what they did was they
10 adopted an equivalent equipment list that was created by
11 one of the trade associations, ISPE, that makes it easier
12 for drug manufacturers when they make equipment changes.
13 They have a list of equivalent equipment that FDA
14 recognizes that way.

15 The Center for Devices and Radiological Health,
16 which is another arm of the FDA, recognized a series of
17 standards and tests set non-FDA organizations which device
18 developers can select from when developing data to show
19 their products work. Of course, it would be beneficial to
20 small businesses if any such standards which are not FDA,
21 and therefore not on the internet, or not assessable
22 without cost, would be affordable to small businesses.

23 In the Center for Device Evaluation and
24 Research also integrated their quality system regulation

1 820, which is the device equivalent of 110, and for
2 example, they said that device companies have to review
3 compliance and if a complaint meets the level that has to
4 be reported under the medical device reporting regulations,
5 803 and 804, then they have to report it.

6 So it's linked right from quality system to the
7 other regulation. That's just an example of the kind of
8 integration and linkage that I'm talking about. And the
9 cosmetic regulations incorporate by reference the cosmetic,
10 toiletry and fragrance association dictionary which is the
11 list that FDA recognizes of official acceptable names that
12 you can put on the cosmetic ingredient list. So that's
13 another example of making it easier for a business to
14 comply. And, I just thought of another one in listening to
15 all the conversation here and the talk about globalization
16 and how to create a regulation which is understandable to
17 foreign manufacturers.

18 Actually, the FDA has done this. In working
19 with the international conference on harmonization in the
20 drug area, because Japan, the E.U. and the U.S. created an
21 active pharmaceutical ingredient guide that all three
22 entities agree and have implemented, and that explains how
23 to make active pharmaceutical ingredients that comply with,
24 in our case, the FDA requirements. So there is a way, and

1 there are examples on how to cooperate internationally
2 that, you know, that we can take advantage of.

3 I've heard so often from small businesses that
4 they want to comply. They just want to know what to do.
5 The FDA needs to hear more from small businesses about how
6 the current GMP effects their ability to comply, and what
7 FDA might do to clarify its regulatory requirements and
8 integrate them into a practical information system that
9 facilitates compliance. If the FDA does not incorporate
10 such specificity into the regulation itself, it could help
11 small businesses by a better articulated, clear and
12 understandable overall information system that is organized
13 intuitively or in a more user-friendly manner and that
14 supports compliance with the regulation. Thank you.

15 DR. ZINK: I'd like to introduce our last
16 speaker, Dr. Clark Nardinelli. Clark has been with FDA
17 since 1995. He's an economist and serves as team leader
18 for Economics in CFSAN. He's worked on cost benefit
19 analysis and small business effects for CFSAN regulations
20 including foods, dietary supplements, infant formula and
21 others. Prior to joining FDA, Clark taught Economics at
22 Tulane, University of Virginia, Clemson, and the University
23 of Maryland. Clark? I want to say one thing. While all
24 this talk here is directed at small business, large

1 business should take stock of this, too. This is an
2 excellent road map of how to make an effective comment that
3 we can really use.

4 DR. NARDINELLI: Yes, as Don said, I'm here to
5 talk to you about how to comment on regulations. My sub-
6 title is advice to small businesses, but large businesses
7 are welcome to listen as well. Let me emphasize that
8 comments are how businesses can participate in FDA rule
9 making. This is before the rule even comes out. This is
10 how you can actually play a role in the development of our
11 regulations.

12 Now, two laws require FDA to ask for and
13 consider comments and concerns particularly of small
14 businesses. These are the Regulatory Flexibility Act of
15 1980 and the Small Business Regulatory Enforcement Fairness
16 Act of 1996. These acts require us to ask for comments and
17 also they require us to consider the possibility of
18 different regulatory requirements for small and large
19 businesses, and in fact, even different regulatory
20 requirements tailored, not even just the large versus
21 small, but to maybe a range of size of businesses, so we
22 often use three categories. We will use a very small
23 business category, a small business category, and then
24 everybody else, I guess the large category.

1 Now, when commenting on potential provisions
2 that might go into a modernized good manufacturing
3 practices regulation, we have some suggestive questions for
4 you to consider. First of all, is there a need for the
5 requirement? Secondly, what will you do to comply with the
6 requirement? Another thing to think about is do you think
7 the requirement will accomplish the stated goals? So, in
8 our modernization of food GMPs, the stated goals are fewer
9 recalls and fewer human illnesses associated with the
10 microbiological, physical and chemical hazards that a
11 modernized GMP will attempt to reduce. And also, are there
12 other ways to accomplish these goals? We are looking for
13 the best way to get there, not for a particular set of
14 rules, but for a particular set of outcomes.

15 Now, when you submit a comment, it's very
16 helpful to us if you describe how the provision will affect
17 you. How will it change how you carry out your business?
18 But in doing so, remember too, that comments and
19 information submitted are available to the public usually
20 on our website, so don't submit sensitive or private
21 information that you don't want in the public domain.

22 Now, we use this data and other information
23 that you submit to help estimate the costs of regulations
24 for small and for large businesses as well, so data can be

1 particularly helpful would be changes in tasks that you
2 perform because of a particular provision or requirement.
3 The number of employees affect it. Time to carry out a
4 provision. And also, the type of your employees who might
5 be affected by a particular requirement. Is it management,
6 is it quality control, or production workers? Let me give
7 you an example.

8 Training. Let's suppose that because of a
9 particular provision, you'll need to train workers in a new
10 procedure. Well, we can divide training into two types of
11 costs. One-time development cost, where you learn about
12 the provision and plan how to train workers. And then the
13 ongoing costs of the training itself, which could be on a
14 weekly, monthly or even an annual basis. I've just put up
15 a very simple numerical example, but numbers help. So, in
16 my numerical example, let's suppose two managers spend two
17 days developing the training, learning about the provision,
18 and we'll say, again, hypothetical cost, this comes out to
19 an \$800 one-time training cost, just to set it up. And
20 then, the ongoing training involves, we'll say one hour per
21 worker per month, and there are eight workers who will have
22 to undergo this, so that comes out to \$1,500 per year.

23 This kind of calculation, of course, may be
24 more complex, but this really, really helps us. This can

1 be a very effective comment.

2 Okay, so let me conclude by just a short list
3 of do and do not's for comments. Do send specific numbers
4 if it's possible without sending in sensitive information.
5 Do send comments in on time. We do have time limits. Do
6 send comments to the Docket. In the meeting notice,
7 there's an actual Docket number that you should refer to.
8 Do, if possible, send combined comments, perhaps through
9 associations.

10 Surveys are very useful. Do not, let me repeat
11 again, do not send sensitive information and do not send
12 unsupported opinions. We know that we have regulations
13 that people like or don't like. It really isn't terribly
14 helpful just to tell us you hate the regulation. Okay. I
15 look forward to getting your comments. Thank you.

16 DR. ZINK: Before I open up to public comment,
17 I'd like to remind everybody that some of you may have
18 gotten here early, before we had our registration or our
19 attendance sheet out front. If you didn't get a chance to
20 sign in as an attendee, please do that before you leave.
21 We'd like to know everybody who came.

22 I'm aware of two individuals that would like to
23 make a public comment. It's not a problem if there's
24 somebody here that I'm not aware of. I will give anybody

1 that wants to a chance to comment, but the way I'll handle
2 this is the ones that I'm aware of, I'll just take them in
3 turn as I became aware of them, and invite them up, and I
4 guess the first commentor I'd like to invite up is Mr. Joe
5 Corby of the Association of Food and Drug Officials. Joe?

6 MR. CORBY: Thank you, Dr. Zink. I'm a
7 volunteer and serve as the Director of Public Policy for
8 the Association of Food and Drug Officials, AFDO, and I'm
9 please to come here today to provide comments on behalf of
10 that organization.

11 AFDO is the preeminent organization in the U.S.
12 of federal, state and local regulatory officials having
13 promoted science-based food safety through the development
14 of model laws and regulations in providing uniform training
15 over its 108 year history. AFDO is well-recognized for
16 having advocated an integrated food safety system for the
17 U.S. to eliminate duplication and gaps in our current
18 system of regulating foods. It is from this perspective
19 that AFDO is providing comments relative to the proposal to
20 modernize what we believe are critical regulations.

21 Many states have adopted 21CFR, Part 110 in
22 whole or in part, and it is generally recognized that this
23 regulation serves as a foundation to others which have been
24 promulgated at the state level. Regulations specific to

1 smoked fish, custom slaughter houses, acidified foods, food
2 salvage dealers, and other food establishment types are
3 built from the regulatory standards provided in Part 110.
4 For this reason, AFDO believes these regulations must be
5 comprehensive, science-based, and have a clear food safety
6 focus. Not only do these regulations serve as a foundation
7 for these other state regulations, but they also provide a
8 prerequisite foundation for mandated Hassip systems. AFDO
9 has always believed that Hassip is systematic and the
10 concepts of Hassip should be employed universally to all
11 food industry sectors. Good manufacturing practices as a
12 recognized prerequisite to Hassip should also be
13 universally applied.

14 Undoubtedly, uniformity among all regulatory
15 agencies is very important to FDA, to the states, certainly
16 to industry, and to consumers. As states conduct more than
17 80 percent of food safety inspections at food processors
18 and distributors, and approximately 8,000 contract
19 inspections for FDA, AFDO believes FDA must seek buy-in
20 from the states on what proposed new changes our philosophy
21 the new GMPs may have. While AFDO strongly believes there
22 is reason to update these important regulations, we also
23 recognize the value and flexibility their results from the
24 broad fashion in which these regulations are written and

1 can be interpreted. From a regulatory perspective, this is
2 a true strength of the regulation. Because of this, there
3 is an excellent regulatory history at the state level
4 associated with the application of the GMPs. This is
5 particularly true with Section 110.80, Processes and
6 Controls.

7 This section has allowed states to require food
8 plants to take all reasonable precautions to assure
9 manufacturing practices do not contribute to contamination.

10 Absent such reasonable precautions, enforcement actions
11 are taken until compliance is fully accomplished.

12 Additionally, this section requires manufacturing,
13 packaging and storage to be conducted under controlled
14 conditions, and this is allowed state programs to take
15 appropriate intervention steps when it is believed that
16 healthy consumers may be impacted.

17 Examples of this: New York was able to
18 prohibit the processing of uneviscerated fish following
19 botulism outbreaks that occurred there in the late 80's and
20 early 90's, prior to New York promulgating specific
21 regulations. Many states have been able to require the
22 refrigeration of shell eggs, following the outbreak of
23 salmonellosis that have occurred in their states. And also,
24 many states are able to require HACCP concepts within the

1 structure of a scheduled process for food processing plants
2 where Hassip plan requirements are not mandated. Typically
3 these scheduled processes are developed by processing
4 experts, land grant universities or colleges and trade
5 associations.

6 Food safety is always evolving as a result of
7 emerging pathogens and new control technologies.
8 Additionally, many new issues and concerns such as food
9 allergens remind us how critically important sanitation,
10 labeling and good manufacturing practices in food plants
11 are. We believe Part 110 must also evolve, and updating
12 this regulation is appropriate in our view. We offer the
13 following specific recommendations: 1) As Part 110 is a
14 regulation and not a guideline, we believe any requirements
15 within this document must be mandated in a context of
16 "shall" and not "should".

17 This, in our opinion, would have a much greater
18 impact on strengthening the regulation and creating
19 uniformity between state and federal regulatory agencies.

20 2) As a GMP serves as a prerequisite foundation for Hassip
21 systems, and it is well recognized that Hassip cannot work
22 effectively without food manufacturing firms adhering to
23 them, AFDO would like to see the GMPs evolve from more of a
24 quality control system to more of a required strategy for

1 food safety intervention. Much of what we find weak in
2 Part 110 is its focus on certain areas on quality issues
3 rather than food safety issues. 3) Definitions for bad or
4 blanching and quality control operations are examples of
5 what we mean about quality issues, and these definitions to
6 us seem out of place. Definitions for ready-to-eat foods,
7 Hassip plan, food allergens.

8 A sanitation standard operating procedure would
9 seem more food safety focus inappropriate for occluding the
10 regulation. We also believe these definitions within the
11 document should be uniform with other federal food safety
12 regulations. 4) Food plants and manufacturers that handle
13 high-risk foods should be required to meet a higher
14 standard. For plants whose products are identified as
15 high-risk for listeria monocytogenes, AFDO believes that a
16 formalized action plan to effectively control or minimize
17 the potential for this pathogen contaminating finished
18 product should be developed and implemented by them. AFDO
19 has just recently endorsed a plan developed by the smoked
20 seafood working group of the National Fisheries Institute
21 and the National Food Processing Association which we have
22 included in our own cured, salted and smoked fish GMP
23 guideline document. 5) FDA should require food safety
24 competency and food safety training for select personnel in

1 food plants, particularly where high-risk foods are handled
2 or where food plants are unable to gain compliance. 6)
3 AFDO supports lowering cold-holding temperatures for
4 potentially hazardous foods to 41 degrees Fahrenheit to be
5 consistent with not only the FDA's own food code, but many
6 of the state requirements. 7) The regulations must remain
7 flexible enough to allow new technologies for combating
8 food safety concerns to be introduced.

9 And finally, AFDO recognizes that the
10 regulatory community will be changed fundamentally by
11 revising these regulations, because much of what we do in
12 our food protection strategies is guided by law which stems
13 in many parts from Part 110.

14 We view FDA's efforts here as very critical,
15 and we are thankful for the opportunity to comment. Thank
16 you.

17 DR. ZINK: Dr. John Rushing, North Carolina
18 State University, Department of Food Science.

19 DR. RUSHING: Thank you, Dr. Zink. Ladies and
20 Gentlemen, I'm afraid my comments don't, are not as
21 eloquent or as organized as the previous speaker's. Some
22 of them were developed as we were talking here, but I
23 wanted to kind of get some things on the floor if I could.

24 I am a professor of food science. I'm a

1 department extension leader of food science at North
2 Carolina State University. I teach a course, a generic
3 course in good manufacturing practices, and a generic
4 course in Hassip at NC State, and one of the requirements
5 that I have is students have to deal with the different
6 regulations and critique them for me, and I get some
7 interesting perspectives on how these regulations are
8 written and how they're carried out. I think the students
9 find a lot of things that we, ourselves, would find in
10 these things.

11 There's three things that I'm interested in
12 asking that we consider. One of them you've heard before.
13 I'd like to see it consistent across the commodities. I'd
14 like to see these regulations where they're harmonized not
15 only within the regulations here in the United States, but
16 with international Codex requirements. In all cases, I
17 think that these regulations are only as good as the people
18 who are putting these things together in the plants.

19 So, the aspects of training and supervision are
20 very important, and as you heard before, there was a
21 request that there be some method of determining
22 competency. I think that there needs to be a requirement
23 for competency of those people who are actually supervising
24 sanitation and training the people in the plant in

1 sanitation.

2 The big question that I think comes up in good
3 manufacturing practices now after we've seen the seafood
4 Hassip regulations and the juice Hassip regulations is what
5 do you do with SSOPs? Should they be incorporated into the
6 GMPs? I think that we should really consider possibly
7 removing those from those two Hassip regulations and
8 putting the SSOP requirement into the GMPs so that you'll
9 have a good definition across the board throughout the
10 nation, and what the components are of each category.

11 One of the things that we found when we were
12 taking a look at the Hassip requirements for dairy
13 manufacturing is that there seemed to be a confusion when
14 we were trying to use the same SSOP requirements that
15 seafood and juice use between adulteration and
16 contamination.

17 I think we all know in our mind what
18 adulteration and I think we all know in our mind what
19 contamination is, and I think I saw a slide up here that
20 generally said that contamination dealt with
21 microbiological problems and adulteration dealt with other
22 issues. I don't think that we have consistent definitions
23 there and those things need to be clarified in my thoughts.

24 The next point that I'd like to make is that

1 Hassip does have some shortcomings. I'm very much a
2 proponent of Hassip. I've worked very hard to help
3 implement the Hassip program in dairy manufacturing. I've
4 also been on the Hassip committee that put together the
5 training programs for the juice Hassip. One of the things
6 that is a shortcoming in Hassip is our processing plants
7 simply do not have the technical expertise. They don't
8 have the technical expertise to do a hazard analysis in
9 many cases. They don't have the technical expertise to
10 design the appropriate controls for critical control
11 points, and many times, they don't have the technical
12 expertise for validation of the process. We need a lot of
13 guidance there. I don't know whether that needs to come
14 from a regulation or whether it needs to come from a
15 guidance document, but we do need to take care of that.
16 Somehow we have to develop that expertise or have enough
17 guidance for the plant that that expertise can be followed.

18 And, the last thing that I'd like to mention,
19 and it has already been mentioned, too. I've been on a lot
20 of committees over the years, where you bring experts in
21 from a lot of different industries and buddies like my
22 friend here from Kraft, and my friend here from Dean Foods.

23 Those guys show up at these meetings. Their expertise is
24 unquestioned. Their companies are committed to the things

1 that they know have to be done. Their companies know how
2 to do it. Smaller companies simply don't have that kind of
3 expertise. They don't know what needs to be done, and I
4 want to ask that you'll do what you can when you put this
5 together to bring those companies along, so that they can
6 get the things accomplished that we want to get
7 accomplished. Our goal is not necessarily compliance. Our
8 goal is to reach a certain level of public health. But I
9 want to thank you very much for listening to the comments.
10 Thank you very much, appreciate it.

11 DR. ZINK: Is there anyone else that would like
12 to make a public comment? You don't have to come to the
13 podium, you can do it just from one of those microphones,
14 if you like. Okay, if not, what I'd like to do is begin to
15 wrap up the meeting by briefly reviewing some of the things
16 I think that we heard you say. I want to emphasize that a
17 transcript is prepared and we've have captured every
18 comment and every presentation, so if I don't mention it
19 here, it's probably a deficiency of my note taking and
20 ability to review it on the fly rather than us not being
21 interested in hearing it.

22 We've heard from a number of speakers that GMPs
23 are important. They're important to state regulators.
24 They're too important to the industry. They reflect past

1 learnings and how to prevent problems in the future. I
2 think it's been said that they don't need major change,
3 that one of their great strengths is the broad way in which
4 they are written now and that we shouldn't lose that in any
5 revision or modernization. We should keep them from being
6 too specific. Where specificity is needed, perhaps this
7 can be done with guidance. There is a great value in
8 guidance, perhaps in supplying some of the technical
9 information that might not be needed, but it might not be
10 available, excuse me, to everyone in the industry.
11 Particularly, the industry needs help in how to look at
12 their operation and identify hazards, and use this hazard
13 identification information to tailor the GMP program to
14 their operation. Several speakers have told us that the
15 GMPs should be compatible with Codex. This is certainly
16 something that we were thinking and something that's going
17 to get, you know, very strong consideration as we try to
18 modernize this regulation.

19 We've also heard that the GMPs predated our
20 appreciation for food allergens and the need to control
21 them. Presently there are regulations about food labeling.

22 There aren't presently any regulations about management
23 practices or requirements for how to go about being sure
24 that food allergens, undeclared food allergens don't get

1 into food products, and that's an area that we're going to
2 be giving attention to.

3 There are no regulations regarding the use of
4 rework, specifically. There is no standardization of "may
5 contain" statements on labels or criteria for when to use
6 them. Some of you expressed concern that where a food
7 safety focus exists, this should be in the regulation to
8 ensure compliance rather than in a guidance document. That
9 where possible, we should revise the format of the
10 regulation to state the hazard connected with the control
11 and arrange it in a way that groups control requirements
12 with like-hazards.

13 Current GMPs do not adequately address
14 allergens, another speaker. Training was hit at by a
15 number of speakers. There was generally comments that
16 training should include training on hazard identification
17 and control. That this should include allergens. That
18 training should be especially important for those
19 responsible for supervising and conducting sanitation
20 operations.

21 The term "adequate" which is often used in the
22 current regulations is not particularly well-defined and
23 that we should perhaps consider use of words like
24 demonstrated, validated or documented, and that the

1 inclusion of a requirement for records and validation as
2 appropriate is important.

3 The current regulations don't address unique
4 issues associated with transportation and warehousing. I
5 think we would like to hear more in written comments on
6 that about, perhaps unique segments of the food industry
7 that should be included in this. There was a suggestion to
8 change this to reflect some of the temperature requirements
9 currently in the food code, particularly for potentially
10 hazardous foods. There was a comment that we strengthen
11 sanitation requirements to include monitoring, verification
12 and record keeping. A request that we define
13 pasteurization requirements in light of some of the new
14 technologies. And require identification of hazards and
15 controls by each manufacturer.

16 There were comments that 21CFR, 110 is very
17 important to each of the states, and that the states have a
18 very significant role in food safety, inspections, and in
19 fact, conduct the majority of food safety inspections, and
20 that the states must buy-in to the types of changes that
21 we're proposing. That GMPs are a foundation for other
22 systems, such as Hassip. There was a suggestion that we
23 examine the use of words "shall" and "should", with greater
24 emphasis on the use of the word "shall". That we should

1 revise definitions, deleting perhaps some inappropriate
2 definitions and adding other definitions, particularly
3 those that have greater food safety impact. That we should
4 consider a more stringent or higher standard for high-risk
5 ready-to-eat foods. There was a suggestion that 41 degrees
6 Fahrenheit would be most appropriate for potentially
7 hazardous foods.

8 I might add we struggle with that definition of
9 potentially hazardous foods from time to time. That we
10 should make the regulation consistent across commodities
11 and with international requirements. That we should
12 require competency, and a number of speakers had mentioned
13 both training and competency, and I do see a difference
14 between those two. It's one thing to receive training.
15 It's quite another to take it in and be competent. That we
16 should make SSOPs a part of the GMPs and perhaps that we
17 should even consider where other areas where we use SSOPs
18 and ensure that our implementation of SSOPs is consistent
19 across the foods we regulate. That there is a problem with
20 a lack of the technical expertise to identify hazards and
21 design control plans and that we need guidance in this
22 area, especially for small companies.

23 And on the matter of guidance, I think we have
24 recognized, we do so with a great sigh because so much work

1 is to be done in drafting guidance documents that can apply
2 in many areas of the food industry. But I think we do
3 recognize the value of guidance documents as a means of
4 interpreting the regulation and how it should be
5 implemented.

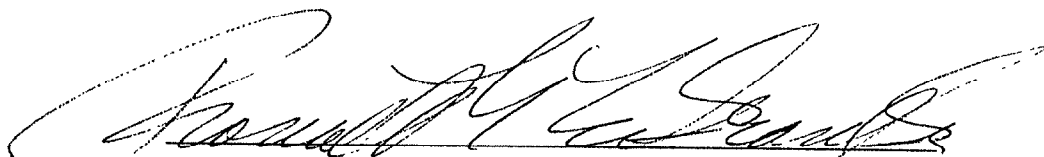
6 With that, I believe, if there are no further
7 questions or comments, we'll go ahead and adjourn the
8 meeting. Thank everyone for coming and please encourage
9 all of you to send us written comments. There's
10 instructions on how to do that in the federal register
11 announcement, and once again, if you did not sign up as an
12 attendee when you came in, please do so on your way out.
13 Thank you very much.

14 (Whereupon the above matter concluded
15 at the hour of 4:25 p.m.)

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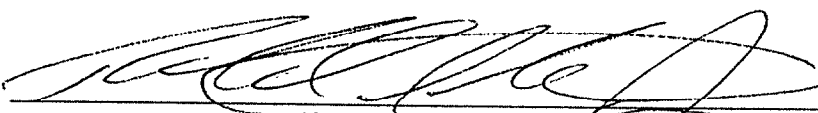
STATE OF ILLINOIS)
) SS.
 COUNTY OF DUPAGE)

I, RONALD N. LEGRAND, SR., depose and say that I am an electronic reporter doing business in the State of Illinois; that I reported verbatim the foregoing proceedings and that the foregoing is a true and correct transcript to the best of my knowledge and ability.


 RONALD N. LEGRAND, SR.

SUBSCRIBED AND SWORN TO

BEFORE ME THIS 11TH DAY OF
AUGUST, A.D. 20 04.


 NOTARY PUBLIC

